K011572

Appendix F. 510(k) Summary

JUN 1 5 2001

8 510(k) Summary

8.1 Identification:

8.1.1 Date of Application:

May 18, 2001

8.1.2 Applicant's and Name and Address:

Corey Stewart
Quality Control Manager
Digirad Corporation
9350 Trade Place
San Diego, CA 92126

8.1.3 Telephone and Fax Numbers of the Applicant

Telephone: (858) 537 – 2118
Fax: (858) 549 – 9789
Email: cstewart@digirad.com

8.1.4 Signature

Corey Stewart

Date 5/18/01

8.2 Device name and classification

8.2.1 Classification Code:

90 KPS

8.2.2 Panel Identification:

Radiology

8.2.3 Proprietary Name:

Quantitative Gated SPECT (QGS)
Quantitative Perfusion SPECT (QPS)

SK49

8.2.4 Common Name:

Gamma Camera System

8.2.5 Classification Name:

System, Emission Computed Tomography

8.2.6 Classification Class:

Class II Product

8.2.7 Substantial Equivalence

The proposed device and the predicate devices have the same indication for use and functionalities. The QGS and QPS proposed is the same application as the QGS and QPS sponsored by SMV America. The QGS and QPS proposed shall be analyzing the same data as the existing Digirad 2020tc SPECT Imaging System.

Table 8.1 Predicate devices

	Existing Digirad 2020tc SPECT Imaging System	QGS/QPS Sponsor: SMV America
Product Code	90 KPS	90 KPS
510(k) Number	K982855	K003358

8.2.8 Device Description

The QGS/QPS programs are independent, standalone software applications developed by Cedars-Sinai Medical Center for the display and quantification of cardiac SPECT data. The programs will run on the computer systems with a PC architecture, the Microsoft® Windows® operating systems and a third party X-server software.

The QGS/QPS programs take reconstructed tomographic slices of the left ventricle generated from gated and/or non-gated cardiac SPECT studies and display the images along with automatically generated quantification.

QPS analyzes myocardial perfusion by quantifying defect extent and severity using gender and isotope-specific normal limits. 2D and 3D perfusion maps are automatically generated.

QGS analyzes myocardial function by quantifying global and regional ejection fraction, wall thickening, and left ventricular volume at end-diastole and end-systole. 2D and 3D images of perfusion and thickening are generated.

8.2.9 Intended Use

The Quantitative Gated SPECT (QGS) and Quantitative Perfusion SPECT (QPS) programs are intended for use in the display and quantification of myocardial perfusion and functional parameters from cardiac SPECT data.

8.2.10 Testing

Functionality tests were conducted to demonstrate that each software application functioned as per its specifications. Computer platform test was performed by running QGS and QPS programs on computer systems with proposed platform using a standard Cedars-Sinai test case. The test passed with the actual results matching the Cedars-Sinai results.

Clinical validation on QGS and QPS programs has been conducted by Cedars-Sinai Medical Center and published in the Journal of Nuclear Medicine, Vol. 41, No.4, April 2000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2001

Corey Stewart
Quality Control Manager
DIGIRAD Corporation
9350 Trade Place
San Diego, CA 92126-6334

Re: K011572
QGS (Quantitative Gated SPECT) and QPS
(Quantitative Perfusion SPECT)
Dated: May 18, 2001
Received: May 21, 2001
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Stewart:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

APPENDIX G. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 011572

Device Name: QGS (Quantitative Gated SPECT) and QPS (Quantitative Perfusion SPECT)

Indications For Use:

The Quantitative Gated SPECT (QGS) and Quantitative Perfusion SPECT (QPS) programs are intended for use in the display and quantification of myocardial perfusion and functional parameters from cardiac SPECT data.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011572